

C. Remarks

The claims are 48-61, 63-66, 73-77, 79 and 80, with claims 48 and 63 being independent. Reconsideration of the present claims is respectfully requested.

Claims 48-53, 63, 73 and 79 stand rejected under 35 U.S.C. §102(a) as being unpatentable over Ke (U.S. Patent No. 6,352,970). Applicant respectfully traverses this rejection and hereby incorporates by reference all previously advanced arguments related to this rejection.

Ke fails to disclose each and every element of the presently pending claims. Specifically, Ke fails to disclose a step wherein a drug consisting only of one or more bisphosphonates is administered to a human subject to promote bone growth; Applicant's previous arguments make it clear that no other step, by which an active agent (other than one or more bisphosphonates) can be administered for the promotion of bone growth, falls within the scope of the present claims. The Examiner takes the position that Ke's disclosure of treating a bone fracture with a combination of leptin (or a leptin mimetic) and a bisphosphonate inherently teaches the present invention. Applicant respectfully submits that the Examiner's position is misguided. Ke's explicitly acknowledgment that bisphosphonate itself is not responsible for the promotion of bone growth or new bone formation at a fracture site counters the Examiner's position. ("All approved therapies and clinically advanced candidates including . . . bisphosphonates . . . act to prevent bone loss by inhibiting bone resorption, but these agents cannot restore bone mass." Column 2, lines

14-18.) Ke, therefore, does not explicitly or inherently teach the use of a bisphosphonate to promote bone growth; leptin or a leptin mimetic performs that function in Ke.

In sum, it is clear that Ke does not disclose or suggest the use of only bisphosphonate(s) to promote bone growth at a fracture site. In direct contrast, the drug of the present invention consists only of at least one bisphosphonate. Accordingly, Ke does not disclose each and every element of the present claims and cannot, therefore, anticipate those claims. Withdrawal of the §102 rejection based upon Ke is respectfully requested.

Claims 48-50, 52, 53, 63-66, 74 and 80 stand rejected under 35 U.S.C. §102(b) as being unpatentable over Geddes (WO 93/11786). Applicant respectfully traverses this rejection and hereby incorporates by reference all previously advanced arguments related to this rejection.

Simply put, Geddes fails to disclose each and every element of the presently pending claims. Specifically, Geddes fails to disclose the use of a drug which consists only of one or more bisphosphonates; Applicant's previous arguments make it clear that no other step, by which an active agent (other than one or more bisphosphonates) can be administered for the promotion of bone growth, falls within the scope of the present claims. What is more, Geddes' disclosure of the administration of a bisphosphonate to a subject with a history of atraumatic fractures is not the same as a teaching (or suggestion) of administration to a subject with a bone fracture. The patient with the history of atraumatic fractures disclosed by Geddes is not said to have had a current fracture which was

addressed by the treatment protocol of Geddes; instead that patient was treated for osteoporosis, which is quite different from promoting bone growth at a fracture site.

Hence, it is clear that Geddes does not disclose or suggest the use of bisphosphonate(s) alone or the use of its combination bisphosphonate/parathyroid hormone therapy at the site of a bone fracture. In direct contrast, promotion of bone growth at the site of a bone fracture with a drug consisting of at least one bisphosphonate is required by the present claims. Accordingly, Geddes does not disclose each and every element of the present claims and cannot, therefore, anticipate those claims. Withdrawal of the §102 rejection based upon Geddes is respectfully requested.

Claims 48-52, 63 and 64 stand rejected under 35 U.S.C. §103(a) as being obvious over Yates (U.S. Patent No. 5,646,134). Applicant respectfully traverses this rejection and hereby incorporates by reference all previously advanced arguments related to the corresponding §102 rejection based on Yates.

Yates fails to disclose or suggest at least certain key features of the presently pending claims. Specifically, Yates provides no teaching with regard to the use of a bisphosphonate to promote growth at a fracture site. Yates is concerned only with preventing periprosthetic bone loss by the administration of a bisphosphonate bone resorption inhibitor. Yates' mention (in its background section) of the occurrence of approximately 5 million fractures per year can, in no way, be interpreted as a teaching of the use of bisphosphonates at the site of a bone fracture - it is a mere statement of

background fact. The entire disclosure of Yates makes clear the only locus upon which the bisphosphonate is to act according to Yates:

- “... for the prophylaxis and treatment of failure of joint prostheses”
- col. 2, lines 48-49
- “... symptomatic failure of a joint prostheses or internal fixation device” - col. 2, lines 55-56
- “... in the periprosthetic bone area of a medical implant device” -
col. 3, lines 20-21
- “By the term ‘periprosthetic bone area’ as used herein is meant the area of bone which is in [sic] contact with the medical implant device or in the immediate proximity thereof.” - col. 3, lines 22-24
- “... useful for improving implant fixation, for example, for improving in growth of new bone into a metal prosthesis in joint reconstruction or orthopedic implants” - col. 4, lines 11-13

Hence, it is clear that Yates does not disclose or suggest the use of its bisphosphonate therapy at the site of a bone fracture. What is more, Yates in no way discloses or suggests that a bisphosphonate could be used in the absence of an implant or other device. In direct contrast, promotion of bone growth at the site of a bone fracture is required by the present claims. Withdrawal of the §103 rejection based upon Yates is respectfully requested.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue of the present case is respectfully requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Elizabeth F. Holowacz/
Elizabeth F. Holowacz
Attorney for Applicant
Registration No. 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200